REMARKS

Applicant respectfully requests reconsideration of the application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 1, 2, 17, 19 and 21 are amended to recite that the low molecular weight drug has a molecular weight of less than about 300 daltons. Support for these amendments may be found throughout the specification as filed, such as in the paragraph bridging pages 7-8. Claim 1 also is amended to recite that at least one polymer is a high shear resistant acrylic-based pressure-sensitive adhesive polymer. Support for this amendment may be found throughout the specification as filed, such as at pages 11-13. Claim 6 is amended to correct a typographical error. Claim 22 is added to recite a specific embodiment. These amendments are made without prejudice or disclaimer, and Applicant reserves the right to pursue any canceled subject matter in one or more applications with the same rights of priority as the instant application.

Upon entry of these amendments, which do not introduce any new matter, claims 1-22 will be pending. These claims are presented for reconsideration.

II. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The specific grounds of rejection are addressed below.

A. "At Least One Of Which Is A Low Molecular Weight Drug"

The Office Action rejects claim 1 as allegedly indefinite for reciting "at least one of which is a low molecular weight drug." According to the Office Action, "the word 'low' renders the claim indefinite." While not acquiescing in the propriety of the rejection, Applicant has

amended the claims to specify that the low molecular weight drug has a molecular weight "of less than about 300 daltons." Thus, this rejection is obviated.

B. "Below Processing Temperatures"

The Office Action rejects claim 1 as allegedly indefinite for reciting "below processing temperatures." According to the Office Action, "the phrase renders the claim unclear because this processing temperature is not recited." Applicant respectfully traverses this rejection.

In assessing compliance with 35 U.S.C. § 112, second paragraph, the "essential inquiry . . . is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity." MPEP § 2173.02 (emphasis added). The claim language must not be considered in a vacuum. *Id.* Instead, the teachings of the prior art and the understanding of the skilled artisan must also be considered. *Id.*

Here, the claims define the claimed subject matter with a reasonable degree of clarity and particularity, and one of skill in the art readily would understand the metes and bounds of the recited "processing temperatures." As indicated in the specification, the "processing temperatures" are the temperatures at which the transdermal compositions are processed. *See* Specification, paragraph bridging pages 10-11. Those skilled in the art will know the processing temperatures being used for a given transdermal system and, therefore, can readily determine whether a given system is substantially free of liquids having a boiling point below such processing temperatures. Thus, the claims do not need to recite specific processing temperatures in order to satisfy §112.

Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

C. "Equal To Or Greater Than The Normal Boiling Points Of The At Least One Low Molecule Weight Drug"

The Office Action rejects claims 1 and 5 for reciting "equal to or greater than the normal boiling points of the at least one low molecule weight drug." According to the Office Action, "[t]he meaning is vague since the drug is not known; there is no way to compare its boiling point." Office Action at 3. Applicant respectfully traverses this ground of rejection.

The claims are clear and definite as written. The skilled artisan readily will understand the metes and bounds of the recitation that the transdermal system be substantially free of water and liquids having a boiling point equal to or greater than the normal boiling points of the at least one low molecular weight drug. For example, when formulating a transdermal system, the skilled artisan may select one or more low molecular weight drugs, at which point her or she will know (or readily could determine) the normal boiling point of the selected low molecular weight drug(s), and thus will know (or readily could determine) whether the transdermal system is substantially free of liquids having a boiling point equal to or greater than the normal boiling points of the selected low molecular weight drug(s). Thus, the claims do not need to recite specific drugs or their normal boiling points in order to satisfy §112.

Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

III. Claim Objections

The Office Action objects to claim 6 for reciting "per cent" rather than "percent." Applicant has amended the claim to correct this clerical error.

IV. Claim Rejections – 35 U.S.C. § 102

A. WO 93/00058 to Miranda *et al.*

Claims 1-6 and 10-21 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by WO 93/00058 to Miranda *et al.* According to the Office Action, "Miranda teaches the shear resistance of 99 hours which is almost the same [as 100 hours] and also teaches that polyacrylate is preferably present in the pressure-sensitive adhesive composition in an amount ranging from about 2-96% by weight and the polysiloxane is present in an amount ranging from about 98-4%, and the composition according to Miranda comprises fillers, and excipients (page 6)." Office Action at 4. Applicant respectfully traverses this rejection.

The '058 application does not anticipate the claimed invention because, for example, the '058 application does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer and (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug and liquid at or about room temperatures, as set forth in claim 1. Indeed, the Office Action fails to identify any particular polymer described in the '058 application that is a "high shear resistant acrylic-based pressure-sensitive adhesive polymer," let alone a teaching to use such a polymer in a transdermal system with a low molecular weight drug, as required by claim 1.

Although the Office Action alleges that "[the '058 application] teaches the shear resistance of 99 hours," that statement is not supported by any citation to the '058 application, and Applicant could find no such teaching in the reference. Indeed, there is no teaching or suggestion in the '058 application of a transdermal system comprising a "high shear resistant acrylic-based pressure-sensitive adhesive polymer" and a low molecular weight drug that is liquid at or about room temperatures, as recited in the instant claims. Thus, this rejection is improper, and should be withdrawn.

Claims 2-21 are further distinguished over the '058 application. Claims 2-18 recite that the pressure-sensitive adhesive transdermal drug delivery system includes one or one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit. Claims 19-21 recite that the pressure-sensitive adhesive transdermal drug delivery system includes one or one or more high shear resistant acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit. The '058 application does not describe compositions comprising such polymers

The '058 application discloses compositions which include acrylic-based polymers such as Duro-Tak 80-1194, Duro-Tak 80-11196, Duro-Tak 80-1197, Gelva 737, and Gelva 738. However, none of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21, or greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit as set forth in claims 2-18. Thus, the '058 application does not anticipate claims 2-21.

B. EP 0 524 776 to Pfister *et al.*

Claims 1-5, 7, 8, 10, 12, and 14-21 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by EP 0 524 776 A1 to Pfister *et al.* According to the Office Action, "[a] blend of polymers are used in the invention [of EP '776] like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+), nicotine-based drug, and co-solvent excipients (page 2, lines 13+)." Office Action at 5. Applicant respectfully traverses this rejection.

EP '776 does not anticipate the invention recited in claim 1 because, for example, EP '776 does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer and (b) a therapeutically effective amount of one or

more drugs, at least one of which is a low molecular weight drug that is liquid at or about room temperatures, as set forth in claim 1. Instead, EP '776 generally relates to silicone-based pressure-sensitive adhesive polymer compositions. *See e.g.*, EP '776 at page 7, lines 33-57.

While EP '776 mentions the use of a "carbomer" in its silicone-based pressure sensitive adhesive, the "carbomer" is not a "high shear resistant acrylic-based pressure sensitive adhesive polymer," as recited in claim 1. Instead, the carbomer is used as a "cohesive strengthening agent" (*e.g.*, a filler) and is dispersed in the silicone pressure-sensitive adhesive to increase cohesive strength. See EP '776, page 5, lines 29-30.

Claims 2-21 are distinguished over EP '776 because, for example, EP '776 fails to teach or suggest an acrylic-based polymer having a shear resistance of 50 hours at 8 pounds per square inch and 72° Fahrenheit, as recited in claims 2-18, or a shear resistance of 50 hours at 4 pounds per square inch and 72° Fahrenheit, as recited in claims 19-21. Although the Office Action alleges that the "carbomer" reads on the recited "high shear resistant acrylic-based polymer," that allegation is pure speculation based solely on the molecular weight of the carbomer.

The Office Action alleges that "since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping." However, a high molecular weight does not necessarily correlate with high shear resistance. As taught in the specification "[t]he shear resistance of the polymer is generally related to the molecular weight of the polymer." Specification at page 23, 1st full paragraph (emphasis added). In other words, shear resistance does not exactly correlate to the molecular weight of the polymer, and it cannot be assumed that polymers with identical molecular weights exhibit identical shear resistance. Anticipation cannot be based on mere probabilities or possibilities. Accordingly, this rejection is improper and should be withdrawn.

V. Claim Rejections – 35 U.S.C. § 103

Claims 1-21 stand rejected under 35 U.S.C. § 103 as allegedly anticipated by EP '776 in view of U.S. Patent No. 5,284,660 to Lee *et al.* In making this rejection, the Office Action cites EP '776 as the primary reference, and cites Lee for teaching a transdermal composition wherein the amount of the drug is 40% of the composition. Applicant traverses this rejection.

As discussed above, EP '776 does not teach or suggest the invention recited in the independent claims. Because Lee does not remedy this deficiency, the combination of EP '776 and Lee does not render the claimed invention obvious. Accordingly, this rejection is improper and should be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions regarding this submission, or should any issues remain, the Examiner is invited to contact the undersigned by telephone in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By Courtenay C. Brinckerhoff

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4094
Facsimile: (202) 672-5399

Courtenay C. Brinckerhoff
Attorney for Applicant
Registration No. 37,288